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UNITED STATES BANKRUPTCY COURT SOUTHERN DISTRICT OF NEW YORK

Chapter 11
Case No. 19-23649 (RDD)
(Jointly Administered)

NAS Children's Ad Hoc Committee Response to ECF Document No. 1167 (Letter Signed by National Advocates For Pregnant Women)

TO: THE HONORABLE ROBERT D. DRAIN UNITED STATES BANKRUPTCY JUDGE

On May 12, 2020, the National Advocates for Pregnant women ("NAPW") filed into the record a letter in response to this Court's initiative on the Emergency Relief Fund.

¹ The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P (0495), SVC Pharma L.P (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

It claimed, without citation to any authority, that "properly controlled research studies, after considering the established risks, have not established that opiates themselves pose specific long-term health risks for children exposed in utero." This unscientific statement is contrary, really the opposite, of what science and medicine have concluded about this innocent population.³

² Rec. Doc 1167 p. 2

³ Williams Obstetrics, 25th Edition, Chapters 5, 12 & 25; American Academy of Pediatrics, 2017; Broussard CS, Rasmussen SA, Reefhuis J, et al; National Birth Defects Prevention Study. Maternal treatment with opioid analgesics and risk for birth defects. Am J Obstet Gynecol. 2011; 204(4): 314.e1-314.e11 and American College of Obstetricians and Gynecologists, 2015 a, 2017d. to name some. ACTA Paediatrica, Consequences of prenatal opioid use for newborns. Kanwaljeet J.S. Anand, Marsha Campbell-Yeo (pp. 1066-1069); New England Journal of Medicine, Drug Use in Pregnancy and Congenital Heart Disease in Offspring. Michael B. Bracken, PhD. Vol. 314 No. 17, April 24, 1986 (pp. 1120-1121); Health Affairs, Marian P. Jarlenski, Elizabeth E. Krans, Joo Yeon Kim, Julie M. Donohue, A. Everette James III, David Kelly, Bradley D. Stein, Debra L. Bogen. 2019 - Jarlenski -Five-Year Outcomes Among Medicaid-Enrolled Children With In Utero Opioid Exposure ISSN 39-2, February 2020, (pp. 247-255); International Journal of Epidemiology, Irma Saxen. Associations Between Oral Clefts and Drugs Vol. 4 No. 1, October 28, 1974 (pp. 37-44); Life Sciences, Behavioral effects of perinatal opioid exposure. Anna Fodor, Julia Timar, Dora Zelena. ISSN LFS-13993, 2014, (pp. 1-8); Centers for Disease Control and Prevention [CDC] - Morbidity & Mortality Weekly Report, CDC Trends in Infant Mortality due to Birth Defects. Lynn, M. Almi, PhD, Danielle M. Ely, PhD, Elizabeth C. Ailes, PhD, Rahi Abouk, PhD, Scott D. Grosse, PhD, Jennifer L. Isenburg, MSPH, Debra B. Waldron, MD, Jennita Reefhuis, PhD. Vol. 69 No. 2, January 17, 2020 (pp. 25-29); Obstetric Medicine, Drugs in Pregnancy and Lactation. Gerald G. Briggs, Roger K. Freeman, Sumner J. Yaffe . ISSN 2:89, 2009, (p. 89);PEDIATRICS, Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome. Mary-Margaret A. Fill, MD, Angela M. Miller, PhD, MSPH, Rachel H. Wilkinson, MPP, Michael D. Warren, MD, MPH, John R. Dunn, DVM, PhD, William Schaffner, MD, Timothy F. Jones, MD Vol. 142 No. 3, September 2018, (pp. 1-8); American Journal of Epidemiology, Exogenous hormones and other drug exposures of. Kenneth J. Rothman, Donald C. Fyler, Allan Goldblatt, Marshall B. Kreidberg. Vol. 109 No. 4, 1979, (pp. 433-439); Centers for Disease Control and Prevention, National Center for Health Statistics, 2007, (www.cdc.gov/nchs/hus.htm). Health_ United States 2007 Statistics. Michael O. Leavitt [Sec. HHS], Julie Louise Gerberding, MD, MPH [Dir. CDC], Edward J. Sondik, PhD [Dir. Nat'l Cent. For Health Stats; Early Human Development, Infants of opioid-dependent mothers_ Neurodevelopment at six months. Laura McGlone, Helen Mactier. Vol. 91 No. 19-21, 2015 (pp. 19-21); NewsOK, Legislators seek to tap opioid settlement funds to plug budget holes. Kayla Branch, Carmen Forman (https://oklahoman.com/article/5661875/legislators-seek-to-tap-opioid-settlement-funds-to-plug-budget-holes), May 8, 2020; PEDIATRICS, Vol. 139 No. 6, June 2017. Maternal Use of Opioids During Pregnanc...tal Malformations_ A Systematic Review. Jennifer N. Lind, Julia D. Interrante, Elizabeth C. Ailes, Suzzanne M. Giboa, Sara Khan, Meghan T. Frey, April L. Dawson, Margaret A. Honein, Nicole F. Dowling, Hilda Razzaghi, Andreea A. Creanga, Cheryl S. Broussard (pp. 1-25); Progress in Biophysics and Molecular Biology, Multigenerational and Transgenerational Inheritance of Drug Exposure - The effects of alcohol opiates cocaine marijuana and nicotine. Nicole L. Yohn, Marisa S. Bartolomei, Julie A. Blendy. Vol. 118 No.21-33, July 1, 2016 (pp. 1-29); PEDIATRICS, Vol. 139 No. 2, February 2017, NAS& HighSchool Performance. Ju Lee Oei, MD, Edward Melhuish, PhD, Hannah Uebel, Nadin Azzam, Courtney Breen, PhD, Lucinda Burns, PhD, Lisa Hilder, MBBS, Barbara Bajuk, MPH, Mohamed E. Abdel-Latiff, MD, Meredith Ward, FRACP, John M. Feller, FRACP, Janet Flaconer, CNC, Sara Clews, CNC, John Eastwood, FRACP, PhD, Annie Li, Ian M. Wright, FRACP. (pp. 1-10); Brain Research, Vol. 839, 1999. Opioid growth factor and organ development in rat and

The lack of even one medical citation supporting this proposition is evidence of its suspect nature. Basic science concerning pregnancy calls it into further doubt as the placenta is the interface between the mother and the baby. It is the place where nutrients, gasses (oxygen and carbon dioxide), metabolic agents (glucose, amino acids, vitamins, and other components), and hormones (HGH, HPL, and others) are transferred between mother and child and child and mother.⁴

We all learned too late that drugs prescribed in the 1950s and early 1960s can and will cross the placenta from mother to baby.⁵ The devastating thalidomide-induced birth defects

human embryos. Ian S. Zagon, Yan Wu, Patricia J. McLaughlin (pp. 313-322); Nature Medicine, Vol. 6 No. 9, September 2000, PainPlasticityAndPrematureBirthAPrescriptionForPermanentSuffering. Kanwaljeet J.S. Anand. (pp. 971-973); Obstetrics & Gynecology, Periconceptional Use of Opioids and the Risk of Neural Tube Defects Vol. 122 No. 4, October 2013, Mahsa M. Yazdy, PhD, Allen A. Mitchell, Md, Sarah C. Tinker, PhD, Samantha E. Parker, MSPH, Martha M. Werler, ScD (pp. 838-844); Continuing Edication in Anaesthesia, Critical Care & Pain, PlacentalStructureFunction&Drug Transfer Vol. 15 No. 2, May 30, 2014, Sara K. Griffiths, BM, BS, FRCA, Jeremy P. Campbell, MBChB, MRCS, FRCA (pp. 84-89); PEDIATRICS, Vol. 144 No. 3, September 2019. Prenatal Opioid Exposure_Neurodevelopmental Consequences and Future Research Priorities. Elisabeth Conradt, PhD, Tess Flannery, MPH, Judy L. Aschner, MD, Robert D. Annett, PhD, Lisa A. Croen, PhD, Cristiane S. Duarte, PhD, MPH, Alexander M. Friedman, MD, MPH, Constance Guille, MD, Monique M. Hedderson, PhD, Julie A. Hofheimer, PhD, Miranda R. Jones, PhD, Christine Ladd-Acosta, PhD, Monica McGrath, ScD, Angela Moreland, PhD, Jenae M. Neiderhiser, PhD, Ruby H.N. Nguyen, PhD, Jonathan Posner, PhD, Judith L. Ross, MD, David A. Savitz, PhD, Steven J. Ondersma, PhD, Barry M. Lester, PhD., (pp. 1-43); Medical Science Monitor, Col. 18 No. 4, 2012,

PreventionOfCommDisordersScreeningPreschoolAndSchoolAgeChildrenForProblemsWithHearingVisions& SpeechEuropeanConsensusStatement. Henryk Sharzynski, Anna Piotrowaska. (pp. SR17-SR21); British Medical Journal, Vol. 358 No. j3326, August 2, 2017, Risk of neonatal drug withdrawal after ...ic medications_cohort study _ The BMJ pdf. Krista F. Huybrechts, Brian T. Bateman, Rishi J Desai, Sonia Hernandez-Diaz, Kathryn Rough, Helen Mogun, Leslie S. Kerzner, Jonathan M. Davis, Megan Stover, Devan Bartels, Jennifer Cottral, Elisabetta Patorno. (pp. 1-19); European Journal of Epidemiology, Vol. 0392 No. 2990, September 1992, Shaw1992Congenitalcardiacanomaliesrelativetoselectedmaternalexposuresandconditionsduringearlypregnancy.pd f. G.M. Shaw, L.H. Malcoe, S.H. Swan, S.K. Cummins, J. Schulman. (pp. 757-760); Brain Research Reviews, The biology of the opioid growth factor receptor.pdf Vol. 38, 2002, Ian S. Zagon, Michael F. Verderame, Patricia J. McLaughlin. (pp. 351-376); Public Health Reports, Vol. 116, 2001, The National Birth Defects Prevention Study.pdf. P.W. Yoon, ScD MPH, S.A. Rasmussen, MD, MS, M.C. Lynberg, PhD, MPH, C.A. Moore, MD, PhD, M. Anderka, MPH, S.L. Carmichael, PhD, P. Costa, MA, C. Druschel, MD, C.A. Hobbs, MD, PhD, P.A. Romitti, PhD, P.H. Langlois, PhD, L.D. Edmonds, MSPH (pp. 32-40); PEDIATRICS, Vol. 125 No. 5, May 2010,; ToleranceAndWithdrawalFromProlongedOpioidUseInCriticallyIllChildren. Kanwaljeet J.S. Anand, Douglas F. Willson, John Berger, Rick Harrison, Kathleen L. Meert, Jerry Zimmerman, Joseph Carcillo, Christopher J.L. Newth, Parthak Prodhan, J. Michael Dean, Carol Nicholson. (pp. e1208-e1225)

⁴ Williams Obstetrics, 25th Edition, Chapter 5

⁵ "Thalidomide was marketed outside the United States from 1956 to 1960, before its teratogenicity was appreciated. The ensuing disaster, with thousands of effected children was instructive of several important teratological principles.

caused science to rethink and conclude that the placenta is an imperfect barrier to drug transfer.⁶ It is now understood that most drugs will eventually cross the placenta and enter the fetal tissues.⁷

Opiates can and do cross the placenta with ease.⁸ And, they can, depending on type, dose, and other factors, enter the fetal tissues within hours of maternal ingestion.⁹ Even a baby only exposed to opioids once during labor can be born sleepy, obtunded, or even dead.¹⁰

But rather than take up a call for the obviously needed program to help children born dependent upon opiates (Neonatal Abstinence Syndrome or NAS children), gain the greatest quality of life, the NAPW claims that ingestion by pregnant women of the highly refined Purdue Oxycodone made from the genetically-engineered Johnson & Johnson Tasmanian Super-Poppy is the equivalent to the opioids used a century ago and nothing further need be done because history has already provided the answer. The NAS Children's Ad Hoc Committee does not know if the NAPW really believes this and, if it does, whether the cause of NAPW's belief is naivete, true medical ignorance, or supposed ignorance in the cause of securing greater funds for another Purdue creditor group or otherwise upsetting the

First, the placenta is not an effective barrier to the transfer of toxic substances from the mother to the embryo. (Dally, 1998). Second, difference species show extreme variability in their susceptibility to drugs and chemicals. Namely, thalidomide produced no defects in multiple rodent studies and was assumed to be safe for humans. Williams Obstetrics, 25th Edition. Kindle location 9736 Chapter 12: Section Known and Suspected Teratogens.; see also *Pharmadyne Laboratories, Inc v. Kennedy*, 466 F. Supp 100, fins 9 & 10

⁷ Opioids have the ability to cross placental and blood-brain barriers, thereby posing risks for fetuses and newborns who are exposed to such drugs in utero. Spontaneous abortion, premature rupture of membranes, preeclampsia, abruption placentae, and fetal death are all potential obstetric complications of prenatal opioid exposure.

⁸ Id

⁹ Ic

 $^{^{10}}$ Williams Obstetrics, 25th Edition Chapter 25, Analgesia and Sedation During Labor

¹¹ Rec. Doc. 1167

mediation process. No matter, their statement is wrong, ill-informed, and without a scientific underpinning.¹²

Before 1986, there were ten major scientific case-controlled studies that reported statistically significant findings that opioids affected fetal development and caused congenital malformations.¹³ There were no large studies with contrary results:

Adverse neonatal outcomes that have been associated with opioid use during pregnancy include preterm birth, small for gestational age, lower birth weight, reduced head circumference, and sudden infant death. Neonatal abstinence syndrome (NAS) is another adverse outcome commonly reported in newborns prenatally exposed to opioids. The incidence of NAS diagnoses increased nearly fivefold in the United States during 2000 to 2012, which suggests an increasing number of opioid-exposed pregnancies. Neuro-developmental outcomes of prenatally exposed infants are an additional area of concern, because a recent meta-analysis reported significant impairments in cognitive, psychomotor, and observed behavioral outcomes in infants and preschool-aged children with chronic intrauterine opioid exposure. The potential teratogenic effects of maternal opioid use during pregnancy are also an area of great public health concern.¹⁴

As advocates for the NAS children, we claim, among other liability theories, that Purdue was obligated to know this science and actually engage in further inquiry before it put

¹² Opiates, alcohol, amphetamines, and barbiturates are all recognized as causing well-documented sequelae including fetal growth restriction, low birth weight, and drug withdrawal soon after birth. American Academy of Pediatrics, 2017; American College of Obstetricians and Gynecologists, 2015 a, 2017d. To suggest, as NAPW does, that use of these substances during pregnancy is without substantial risk is reckless and unscientific;

¹³ Saxen I. The association between maternal influenza, drug consumption and oral clefts. Acta Odontol Scand. 1975;33(5):259–267; Saxen I. Associations between oral clefts and drugs taken during pregnancy. Int J Epidemiol. 1975;4(1):37–44; Rothman KJ, Fyler DC, Goldblatt A, Kreidberg MB. Exogenous hormones and other drug exposures of children with congenital heart disease. Am J Epidemiol. 1979;109(4):433–439; Bracken MB, Holford TR. Exposure to prescribed drugs in pregnancy and association with congenital malformations. Obstet Gynecol. 1981;58(3):336–344; Zierler S, Rothman KJ. Congenital heart disease in relation to maternal use of Bendectin and other drugs in early pregnancy. N Engl J Med. 1985;313(6):347–352; Bracken MB. Drug use in pregnancy and congenital heart disease in offspring. N Engl J Med. 1986;314(17):1120; Shaw GM, Malcoe LH, Swan SH, Cummins SK, Schulman J. Congenital cardiac anomalies relative to selected maternal exposures and conditions during early pregnancy. Eur J Epidemiol. 1992;8(5):757–760; Shaw GM, Todoroff K, Velie EM, Lammer EJ. Maternal illness, including fever and medication use as risk factors for neural tube defects. Teratology. 1998;57(1):1–7; Jick H, Holmes LB, Hunter JR, Madsen S, Stergachis A. First-trimester drug use and congenital disorders. JAMA. 1981;246(4):343–346, and Chasnoff IJ, Hatcher R, Burns WJ. Polydrug- and methadone-addicted newborns: a continuum of impairment? Pediatrics. 1982;70(2):210–213

¹⁴ Exhibit 1: PEDIATRICS Volume 139, number 6, June 2017: e20164131, Maternal Use of Opioids During Pregnancy and Congenital Malformations: A Systematic Review, p. 1

its opioid drugs in commerce and that it was further obligated to market their opioid drugs based on this correct scientific information. Rather, Purdue chose to claim its drugs were safe for long term chronic pain use and downplayed its addictive nature.

On April 22, 2020 in this proceeding, the Emergency Relief Fund (ERF) was put on hold while the mediation moves towards a hopeful resolution. The problems leading to sidelining the ERF are of record: governance and optimal use of the ERF.¹⁵ Why the NAPW, which does not represent an actual Purdue creditor, chose in mid-May 2020 to write to the court, counsel, and the world and offer unsound medical and legal opinions about the NAS children's claims is a mystery.¹⁶

This opioid litigation is part of a complex series of lawsuits, perhaps the largest in history, spanning many state and federal courts, long in time, costly, and despite thousands of hours and resources without the benefit of real resolution involving all aggrieved parties. Taking unfounded pot shots at creditor groups/mediation participants, especially in this court record, as NAPW did, could be seen by reasonable observers as a sad and pathetic

¹⁵ Exhibit 2: Portion of April 22, 2020 Transcript, p. 18 lines 6-19: "The creditors in this case continue to have deeply-held fundamental differences in view as to, among other things, the optimal use of the ERF funds and appropriate governance and it has become clear that attempting to resolve these differences while parties are focused on planned mediation was placing additional strain on that intense, complex, and important process. All parties believe that an ERF is more likely to be successful after additional progress has been made in the mediation. To be clear, while we are pausing consideration of the ERF at this time, it is not cancelled, and all parties have agreed to revisit it once planned mediation has progressed further."

¹⁶ All of NAPW's interest in this bankruptcy proceeding is a mystery. The NAPW is an advocacy organization that seeks to "promote positive change" through [I]litigation and litigation support challenging efforts to establish fetal under the law and expand rights to the war drugs." http://www.advocatesforpregnantwomen.org/main/programs/legal advocacy/ As an advocacy group against fetal rights and against the war on drugs its place in this bankruptcy is highly suspect as this proceeding concerns the bankruptcy of Purdue, a pharmaceutical manufacturer, with many types of unsecured creditors, including children born NAS. Examination of NAPW's mission statement under the well-entrenched rules of organizational standing leads to the unassailable conclusion that NAPW can have no standing as it lacks the required concrete and particularized injury. Generalized harm or interest alone is simply insufficient. Warth v. Seldin, 422 U.S. 490, 498, 95 S. Ct. 2197, 45 L.Ed.2d 343 (1975); United States v. Richardson, 418 U.S. 166, 179, 94 S. Ct. 2940, 41 L.Ed.2d 678 (1974); Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc., 528 U.S. 167, 180–181, 120 S. Ct. 693, 145 L.Ed.2d 610 (2000); Lujan v. Defenders of Wildlife, 504 U.S. 555, 559–560, 112 S. Ct. 2130, 119 L.Ed.2d 351 (1992); Las Angeles v. Lyons, 461 U.S. 95, 111–112, 103 S. Ct. 1660, 75 L.Ed.2d 675 (1983). Whether NAPW will have a role with the now sidelined ERF, is speculative at best.

attempt to interfere with the mediation. Such efforts to thwart the mediation process must be rebuffed.

The NAS Children's Ad Hoc Committee, as advocates for their many thousands of NAS children clients, has two unwavering goals which are legally and scientifically sound: First to secure a medical monitoring program based on the written plan we and our experts have prepared. That plan will follow NAS children to age 18, provide (1) fulsome anonymous medical and educational evaluations for use in their medical and educational settings (2) development of and improve the medical standards of care, educate healthcare providers and educators about NAS, to reduce NAS treatment costs, and (3) educate the public by destigmatizing this population all while protecting the privacy rights of participants and ensuring that the funds set aside for this purpose remain untouched by others who will be inclined to use the funds for a different purpose¹⁷. And second, to secure reasonable and just compensation for the injuries incurred by NAS children and their legal guardians.

To this end, we have retained those experts, most knowledgeable and trusted in their fields. Our primary medical expert, Dr. Sunny Anand, ¹⁸ one of only three physicians selected to nominate the Nobel prize for medicine, has spent his career caring for NAS children. We take the unprecedented step of attaching his expert report used in related litigation to correct

¹⁷https://publicintegrity.org/health/tobacco-settlement-helps-everyone-but-smokers

https://www.cagw.org/thewastewatcher/smoke-what-happened-tobacco-master-settlement-agreement-money

https://www.govinfo.gov/content/pkg/CHRG-108shrg21176/html/CHRG-108shrg21176.html

https://www.upi.com/Top News/US/2018/12/03/20-years-after-settlement-billions-in-anti-tobacco-funds-spent-elsewhere/8971543517818/

https://nytimes.com/2014/10/07/opinion/how-the-big-tobacco-deal-went-bad.html

https://www.tobaccofreekids.org/what-we-do/us/statereport

¹⁸ Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine at Stanford University School of Medicine and Director of the Pain/Stress Neurobiology Laboratory at Children's Hospital Research Institute.

the NAPW's unfortunate statements now of record. Of special importance, is Dr. Anand's call for action:

The immediate effects of the Opioid Crisis [in adult addicts], however, may be strikingly less consequential when compared to its effects on the individuals who were exposed to opioid drugs prenatally, many of whom were diagnosed with NAS. These children, through no fault of theirs, have been condemned to suffer from the short-term and long-term. effects of opioid exposure from birth throughout their childhood, adolescence and into their adult lives. Though the current Opioid Crisis looms large on the thinking of social, medical, or government establishments, its long-term impact is inestimable because of the pervasive and persistent effects of prenatal opioids on all aspects of an individual's development. Their cumulative burden of suffering, and the total impact of their exposures on all facets of our society is so huge and unparalleled in human history that this is truly the real emergency. Unless they are monitored/supported/treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our shortsightedness.19

Dated: New York, New York May 29, 2020

Respectfully Submitted,

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¹⁹ Exhibit 3: Declaration of Dr. Kanwaljeet S. Anand

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